MAY 20 2011

K111052

510(k) Summary
For
syngo Neuro PBV IR

Submitted by:
Siemens Medical Systems, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

April 08, 2011

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. General Information

Importer / Distributor
Siemens Medical Solutions, Inc.
51 Valley Stream Parkway, G-01
Malvern, PA 19355
Establishment Registration Number
2240869

Manufacturing Site
SIEMENS AG Sector Healthcare
Siemensstraße 1
D-91301 Forchheim, Germany

2. Contact Person

Mr. Gary Johnson
Sr. Technical Specialist, Regulatory Submissions
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway G-01
Malvern, PA 19355-1406
Phone: (610) 448 1778 Fax: (610) 448-1787
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3. Device Name and Classification

Trade Name:	syngo Neuro PBV IR
Classification Name:	Accessory to Angiographic X-Ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1600
Device Class:	Class II
Product Code:	90JAA

4. **Legally Marketed Device**

Trade Name:	InSpace 3D Software Option
510(k) Clearance	K011447
Clearance Date	August 3, 2001
Classification Name:	Accessory to Angiographic X-Ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1600
Device Class:	Class II
Product Code:	90JAA

5. **Device Description**

syngo Neuro-PBV IR is a post-processing software application designed to provide the physician with images similar to CT cerebral perfusion in the Interventional Radiography suite. The physician can use these images to visualize blood volume in the vasculature and blood-brain barrier without moving the patient to a CT system. A contrast agent is used to enhance the visualization of the blood flow. As with CT perfusion, the image is further enhanced using color as a reference of the amount of contrast filled blood in an area of the brain.

6. **Intended Use**

Syngo Neuro-PBV IR is an extended software application to the InSpace 3D software option which allows the reconstruction of two-dimentional images acquired with a standard angiographic C-arm device into a three-dimentional image format.

Syngo Neuro-PBV-IR is intended for imaging primarily soft tissue for diagnosis, surgical planning, interventional procedures and treatment follow-up. It is design fro the visualization of contrast enhanced blood distribution in the arterial and venous vessels in the head using color coded relative values for diagnosis.

This software is designed to visually assist physicians in the diagnosis and treatment of vessel malformations (i.e. Aneurysms, AVM's and Stenoses)

7. **Substantial Equivalence**

syngo Neuro-PBV IR Software Application is substantially equivalent to the commercially available Siemens ssoftware application, Inspace 3D. The Inspace 3D software option was described in premarket notification K011447 which received FDA Clearance on August 03, 2001.

The syngo Neuro-PBV IR software is an extension to InSpace 3D and uses the same hardware and software components as the InSpace 3D software option.

8. **Summary of Technological Characteristics of the Principal Device as Compared with the Predicate Device**

syngo Neuro PBV IR is a software extension to Inspace 3D. The principal device syngo Neuro PBV IR features the same Postprocessing software, user interface, archiving and

communication like the predicate Inspace 3D. The design of the syngo Neuro PBV IR is the same as it is integrated into the Inspace 3D task card.

9. General Safety and Effectiveness Concerns

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner.

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing. Furthermore the operators are health care professionals familiar with and responsible for the evaluating and post processing of X-ray images.

10. Conclusion as to Substantial Equivalence

syngo Neuro PBV IR is intended for the same indications for use as the predicate Inspace 3D. syngo Neuro PBV IR Software Application is a further post processing and enhanced visualization technique within Inspace 3D (K011447).

Most of the functionality remains the same as used with the predicate device Inspace 3D (K011447). The functionality is the same or similar to the predicate device with enhanced algorithm to display syngo Neuro PBV IR images.

It is Siemens opinion, that the syngo Neuro PBV IR is substantially equivalent to the Inspace 3D (K011447).

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Gary L. Johnson
Senior Regulatory Technical Specialist
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway G-01
MALVERN PA 19355-1406

MAY 20 2011

Re: K111052
Trade/Device Name: syngo Neuro-PBV IR
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 9, 2011
Received: April 15, 2011

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

SECTION 7

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: _____syngo Neuro-PBV IR_____

Indications for Use:

Syngo Neuro-PBV IR is an extended software application to the InSpace 3D software option which allows the reconstruction of two-dimentional images acquired with a standard angiographic C-arm device into a three-dimentional image format.

Syngo Neuro-PBV-IR is intended for imaging primarily soft tissue for diagnosis, surgical planning, interventional procedures and treatment follow-up. It is design for the visualization of contrast enhanced blood distribution in the arterial and venous vessels in the head using color coded relative values for diagnosis.

This software is designed to visually assist physicians in the diagnosis and treatment of vessel malformations (i.e. Aneurysms, AVM's and Stenoses)

(Please do not write below this line – continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X___ OR Over-The-Counter Use _____
(per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111052